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April 24, 2025

Via ECF

The Hon. Renée Marie Bumb
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*
USDC, District of New Jersey, No. 1:19-md-2875-RMB

Dear Judge Bumb and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on Monday, April 28, 2025.

1. <u>Additional Daubert Hearings Specific to the TPP Trial Are Needed</u>

The Court's April 7, 2025 Opinion (ECF No. 3018) ("TPP Opinion") ordered the parties to be prepared to address whether the deadlines and process put in place for Rule 702 and other motions in the context of the personal injury bellwether cases are sufficient to address the question of general causation for purposes of the TPP Trial "or whether other *Daubert* hearings addressing general causation experts are necessary for the TPP trial specifically." (TPP Opinion at 47). The parties met and conferred on April 21, 2025, and are not in agreement on this question.

The TPP Trial Defendants believe that it is critical for the Court to evaluate the admissibility of that core piece of evidence in advance of a TPP trial and hold specific *Daubert* hearings on the parties' previously-disclosed general causation experts. The Court has recognized that expert testimony addressing cancer causation is "the elephant in the room" which "must be front and center" at the TPP Trial. (*See id.* at 20). Daubert hearings focused on the question of general causation in the TPP proceeding are the only proper way to ensure that "elephant" is properly addressed. None of the parties' proposed expert testimony on general causation has been the subject to a full Daubert inquiry, much less under the recently strengthened Rule 702. The Court previously held only limited Daubert hearings on supplemental opinions provided by a subset of the parties' original general causation experts. And even the narrow group of experts who participated in those hearings have never had their opinions that VCDs are capable of causing

cancer, much less any purported quantification of those risks, tested for fit and reliability in the context of the TPP Trial and under recently amended Rule 702. In this TPP case specifically, Plaintiff has the burden of proving not just a slight or theoretical increased risk of cancer, but rather that the risk presented from the trace amounts of NDMA is substantial enough to present a defect "so fundamental as to render the product valueless."

Moreover, the existing deadlines and processes for Rule 702 motions in the personal injury bellwether cases will only address general causation with respect to the cancers at issue in those cases, as well as specific causation, and are therefore not an adequate substitute for assessing the broader general causation questions that would be "front and center" at a TPP trial.

First, before proceeding with any TPP Trial, the Court should hear from the experts each party intends to have address this core issue of general causation and assess whether the evidence to be offered is both relevant to and fits the essential general causation question as described in the TPP Opinion. The Court's TPP Opinion recognizes that "[t]his entire litigation is about the alleged contamination of lifesaving VCDs with cancer-causing nitrosamines." (*Id.*). Accordingly, "the only viable theory of damages upon which Plaintiffs may hang their breach of express warranty hat" is to present evidence that the nature of the impurities present in VCDs is a flaw so fundamental that it rendered those products worthless at the point of sale, regardless of whether VCDs were effective and achieved their medical purpose. (*See id.* at 18-20).

The TPP Opinion clarifies what will be required at trial, and it is this point on which the parties disagree: the TPP Trial Defendants believe at this phase of the case it is not sufficient that Plaintiffs' experts are able to opine that the compound NDMA is theoretically capable of causing cancer in humans. Rather, Plaintiffs must be able to offer admissible evidence from which a reasonable juror could conclude that the presence of NDMA impurities *in VCDs at the amounts actually present* creates a risk of cancer that is such a fundamental flaw as to render the VCDs worthless.

In 2021, the parties were required to disclose experts on the issue of general causation. (ECF No. 726 at 2-3). In accordance with their deadline of May 3, 2021, Plaintiffs disclosed five experts to address general causation – (1) Stephen Hecht, Ph.D, (2) Mahyar Etminan, (3) Dr. Stephen Lagana, (4) David Madigan, Ph.D, and (5) Dr. Dipak Panigrahy. In response Defendants disclosed nine general causation experts – (1) Dr. Lewis Chodosh, (2) Herman Gibb, (3) Dr. John Flack, (4) Michael Bottorff, Ph.D, (5) Dr. Daniel Catenacci, (6) John Fryzek, (7) George Johnson, Ph.D, (8) Janice Britt, Ph.D and (9) Lee-Jin Wei, Ph.D,.[1]

[1] Defendants note that one of their general causation experts, Dr. Catenacci, was withdrawn, and another, Janice Britt, was excluded at the earlier Rule 702 motion stage. (*See* ECF No. 1958 at 2). Accordingly, Plaintiffs have five (5) and Defendants have seven (7) experts who may be expected to offer general causation evidence at a TPP trial.

The parties filed Rule 702 motions to exclude or limit the opinions of most of these experts.[2] Following completion of Rule 702 briefing, the Court announced in response to Defendants' request for *Daubert* hearings on general causation experts that it would hold limited hearings in a format that "is going to be a little different." (1/5/2022 Hrg. Tr. at 19: 12-13). Specifically, the Court specified that the only direct testimony under consideration at the hearings would be submitted by the proponent of the expert in the form a written affidavit or declaration, with cross examination limited to the content of that affidavit. (*Id.* at 19:21-20:2). Judge Kugler later clarified that the proponent of each expert was able to decide whether to present each expert at the *Daubert* hearings. (2/2/2022 Hrg. Tr. at 26:12-16). Cross-examination by the adverse parties was limited to the points raised in the expert's limited affidavit or declaration, the content of which was determined by the disclosing party. (*Id.* at 27:5-8).

Ahead of the *Daubert* hearings, Plaintiffs submitted certifications and declarations from only three experts, Dr. Panigrahy, Dr. Lagana, and Etminan. (ECF No. 1928). Defendants submitted declarations for two experts, Dr. Bottorff and Dr. Johnson. (ECF No. 1929). Plaintiffs' expert certifications were two, two, and three pages long, respectively. (ECF Nos. 1928-1, 1928-2 & 1928-3).

Consistent with the limited scope of these hearings, the Court repeatedly restricted cross-examination of the Plaintiffs' experts to the content of their certifications: "The point of this is really the question about what [the expert] put in his certification. . . . I'm going to give you some leeway to get some background information done, but let's please focus on [the] certification." (3/2/2022 Hrg. Tr. at 8:14-17; *see also id.* at 21:16-22:8 (limiting counsel from examining Dr. Lagana on his opinions regarding NDEA as NDEA did not appear in his certification); *id.* at 41:21:42:3 (sustaining Plaintiffs' objection to examination on how and whether Dr. Lagana considered dose and length of exposure in his analysis as those topics were not addressed in his certification); *id.* at 42:14-19 (instructing counsel to move on from questions related to Dr. Lagana's assessment of dose response for the cancers alleged because that topic was not addressed in his certification); *id.* at 65:5-66:21 (limiting counsel's questioning of Dr. Panigrahy on identification of a threshold response because that topic was not contained in his certification); *id.* at 90:1-22 (limiting counsel's questioning on topics other than bioavailability, saturation, and first pass metabolism which were addressed in Dr. Panigrahy's certification). Plaintiffs declined to cross-examine either of Defendants' general causation experts on their submitted declarations.

Those truncated proceedings did not provide the Court with the evidence to properly assess admissibility under current Rule 702. As recognized in the TPP Opinion, the December 2023 Amendments to Rule 702 clarified "the rigorous and essential gatekeeping function that is required of district courts." (TPP Opinion at 33); *see* Fed. R. Evid. 702 & advisory committee's note to 2023 amendments. The Third Circuit subsequently held that a *Daubert* process consisting of a single hearing addressing four experts on the same day, with no engagement on the arguments

[2] Notably, Plaintiffs did not challenge or move to limit in any way the opinions of Defendants' cancer biologist, Dr. Lewis Chodosh, or Defendants' epidemiologist, Dr. Herman Gibb.

raised in the underlying Rule 702 briefing as to reliability and fit of an expert's testimony, "fell short of the rigor required by *Daubert* and Rule 702." *Cohen v. Cohen*, 125 F.4th 454, 460-61 (3d Cir. 2025). The district court's gatekeeping responsibilities "are not negated by the existence of an opposing expert, nor can a district court delegate its duty to the parties." *Id.* at 461.

The submission of certifications and affidavits and limited cross-examination solely of those experts who chose to submit such material, confined to the content of those submissions, is not the same as a full *Daubert* hearing that complies with the rigor required by Rule 702 and Third Circuit law. Nor did the Court at the time of the general causation briefing hold the type of hearings which will enable the Court to assess the adequacy of opinions and evidence to be introduced at a TPP Trial. However, with the guidance of the TPP Opinion and to efficiently and effectively assess the core general causation evidence ahead of a TPP Trial, the time for Rule 702 hearings on the parties' general causation experts is now.

Moreover, the abbreviated Daubert hearing held over three years ago did not address the admissibility of the actual opinions and evidence that will ultimately be introduced at a TPP Trial. The TPP Opinion clearly delineated how the crucial general causation evidence will be presented at trial: "Plaintiffs will have the opportunity to present evidence showing the nature and extent of the risks associated with nitrosamine exposure at the levels found in the VCDs. And Defendants will counter with evidence that those risks are minimal or outweighed by the continued therapeutic value of the VCDs." (TPP Opinion at 20). With the guidance of the TPP Opinion, the Court is now in a far better position to hold Rule 702 hearings that will and in order to efficiently and effectively assess the core general causation evidence that the parties seek to admit at relevant to the ahead of a TPP Trial.

The TPP Trial Defendants propose that the TPP trial parties – Plaintiffs, ZHP, Teva, and Torrent – be required to identify which of their previously disclosed general causation experts will be offering evidence on general causation at trial. The Court can then hold *Daubert* hearings in the same fashion as was conducted for the parties' damages experts in September 2024.

The TPP Trial Defendants' proposal will ensure that the Court is satisfied the general causation evidence meets the requirements of qualification, reliability, and fit under Rule 702 and may be admitted and presented to the jury with respect to the essential question of whether "nitrosamine exposure at the levels found in the VCDs" is "a flaw so fundamental that it renders the product worthless." (*See* TPP Opinion at 19-20). As the Court reminded the parties, evidence which may have been sufficient at an earlier stage of the litigation to meet Plaintiffs' burden is not guaranteed to suffice now that Plaintiffs will be "put to their proofs." (*Id.* at 19 & n.13). The efficient administration of this sprawling litigation will be greatly aided if the Court exercises its gatekeeping function and performs this type of analysis under Rule 702 prior to setting or scheduling any further TPP trial proceedings.

To the second question posed by the Court, the existing Rule 702 deadlines and processes currently taking place in the context of the personal injury bellwether trials are not a sufficient substitute for the general causation Rule 702 process the TPP Trial Defendants have outlined above

as parties to the TPP trial.[3] The first and most obvious issue is that the cancers at issue in the personal injury bellwether cases are limited to liver (in *Roberts*), colorectal (in *Garcia*, *Lee*, and *Suits*), and stomach (in *Smalls*). Even if Defendants are to prevail and demonstrate that VCDs containing impurities at the specific levels to which these Plaintiffs were exposed are not capable of causing cancer, it will not resolve the more fundamental question of whether VCDs can cause other types of cancer at other levels of exposure.

The existing expert workup in the bellwether cases also does not currently include Rule 702 briefing and hearings on the parties' previously disclosed general causation experts, which would be needed to assess general, rather than specific, causation. Nor does any expert who has been disclosed in connection with the bellwethers to date opine on the full breadth of impurity levels and likely amounts of exposure to NDMA from VCDs purchased by TPP class members. Finally, the nature of the claims posed in the personal injury bellwether trials does not position the parties to address the core general causation question identified in the TPP Opinion, i.e., whether the presence and level of impurities is a flaw so fundamental as to render the product worthless. In other words, the existing bellwether 702 process (i.e., can valsartan containing NDMA cause specific cancers) does not address whether the valsartan containing NDMA increases the risk of cancer significantly enough to present a fundamental defect rendering the product valueless. For all these reasons, the Court should address general causation for purposes of a TPP trial in separate proceedings.

Plaintiffs Should Not Be Entitled to Disclose New GC or Damages Experts

During the parties' meet and confer, Plaintiffs suggested they should be entitled to disclose new experts for purposes of the TPP trial. All Defendants disagree with that assertion. The deadline for disclosing general causation experts was May 3, 2021, and the deadline for disclosing damages experts was January 20, 2023 (ECF No. 2190). Allowing Plaintiffs to go back to the drawing board on causation and damages experts would set this litigation back years in time and push out the TPP trial even further. The Court's TPP opinion merely clarified the issues to be tried in the TPP trial,

[3] General causation is not a one-size-fits-all issue. Risk to patients, if any, is necessarily influenced by, among other things, the level of nitrosamine impurities detected in the product. Those levels, in turn, widely vary depending on a number of factors, including the Defendant involved and the manufacturing process used to produce the batches of medication received by Plaintiffs. Moreover, there is a stark contrast in the science supporting Plaintiffs' claims depending on whether they involved NDMA versus NDEA. Whereas the Court's prior rulings did not place any limits on Plaintiffs' general causation experts' testimony with respect to NDMA—the impurity upon which the contemplated TPP class trial was to focus—Defendants interpret Judge Kugler's opinion as having restricted Plaintiffs' experts' NDEA opinions to a single cancer type: pancreatic. While Defendants maintain that there is no causal link whatsoever between valsartan that contained trace NDEA impurities and any cancer, Mylan believes the personal-injury bellwether process, coupled with the pending motion to clarify with respect to the Court's NDEA rulings, is sufficient to resolve that specific issue.

based on existing law, and it did not, as Plaintiffs suggest, fundamentally change the nature of the case in any way. Plaintiffs chose to plead and pursue their theory of worthlessness and have disclosed the experts they believed were needed to support such claims. Those experts were long ago disclosed, deposed, and in the case of damages experts, challenged and ruled upon. The Court's imposition of limitations on Dr. Conti's testimony does not warrant a new round of damages experts, just like a proper Rule 702 review of general causation experts to assess fit and reliability in the context of the TPP Trial. under the fundamental flaw analysis, does not necessitate new causation experts. At this stage of the litigation, the Court and the parties should be working to narrow and clarify the issues for the TPP trial, not expanding and reinventing them. Simply put, the exercise of gatekeeping does not open new gates for Plaintiffs.

2. <u>Plaintiffs Lack Admissible Proof Of Damages With Respect To Their Fraud And Consumer Protection Claims.</u>

The Court recently ruled that Dr. Conti's "worthlessness" opinion is inadmissible because it "ignores the 'real world'" and therefore would not be helpful to jurors and "is unreliable in light of its inconsistencies and the stark lack of scientific or economic basis." (Dkt # 3018 at 36-37, 46.) Although the Court specifically limited its ruling to Plaintiffs' express warranty claims, it has asked the parties to address the implications of its decision on "the remainder of the claims" at issue in the TPP class action case, including the TPP Plaintiffs' common law fraud and state consumer protection claims. (*Id.* at 46-47.) As explained below, the reasoning underlying the Court's ruling similarly bars the TPP Plaintiffs from establishing injury (much less damages) for their fraud- and consumer protection-based claims. With respect to common law fraud claims, the majority of the states at issue employ either a benefit-of-the-bargain standard or an "out of pocket" rule that requires proof of the "actual value" of the VCDs received. And the relevant consumer protection laws generally require plaintiffs to present evidence that they suffered an identifiable ascertainable loss—i.e., that the actual value of the VCDs at issue was less than what the TPP paid for it.

First, under the laws of at least 20 of the 23 states at issue, a common law fraud claim generally requires proof of either: (1) "benefit of the bargain" damages; or (2) "out of pocket" loss, both of which require an assessment of the actual value of the VCDs received based on the relative benefits and risks of the medication. (*See* Ex. A (Assessment of TPP Fraud Subclass Group C).) For example, in Colorado, "[t]he 'benefit of the bargain' rule, the difference between the value of the [good] as it actually existed on the day of the sale and its value as it was presented to be, has long been applied as the proper measure of damages for fraud." *Elk River Assocs. v. Huskin*, 691 P.2d 1148, 1154 (Colo. App. 1984). Moreover, actual value turns on the "benefits actually received." *W. Cities Broad., Inc. v. Schueller*, 830 P.2d 1074, 1077 (Colo. App. 1991). The same is true of several other states' fraud laws. *See, e.g.*, *Shaver v. N.C. Monroe Constr. Co.*, 306 S.E.2d 519, 526 (N.C. Ct. App. 1983) ("The proper measure of damages in this case is the benefit of the bargain, which . . . allows him to recover the difference between the actual value of the subject of the representation and the value as represented, and has generally been applied in fraud cases."); *Caseau v. Belisle*, No. PC 01- 4441, 2005 WL 2354135, at *9 (R.I. Super. Ct. Sept. 26, 2005) ("It is axiomatic that the 'benefit of the bargain' rule is the proper measure of damages in a claim for

fraud or misrepresentation" which is "the difference between the actual value of what the defrauded person received and the value which it would have had if it had been as represented.") (citation omitted).

Other relevant states allow plaintiffs to establish damages for fraud using either a benefit-of-the-bargain or an out-of-pocket loss standard, which similarly requires an assessment of the actual value of the product. *See, e.g.*, *Wallis v. Ford Motor Co.*, 208 S.W.3d 153, 155 (Ark. 2005) (Arkansas courts have "applied two measures of damages for common-law fraud: (1) the benefit of the bargain measure . . . and (2) the out-of-pocket measure"); *see also Kind v. Gittman*, 889 So. 2d 87, 90 (Fla. Dist. Ct. App. 2004) (same under Florida law); *Walston v. Monumental Life Ins. Co.*, 923 P.2d 456, 462-63 (Idaho 1996) (same under Idaho law). These states' laws make clear that establishing "out of pocket" loss requires an inquiry into "the difference between the price paid for the [product] and the [product's] ***actual value*** when received." *Wallis*, 208 S.W.3d at 155 (emphasis added); *see also Kind*, 889 So. 2d at 90 ("Either measure of damages requires a plaintiff to prove the actual value of the property at the time of purchase."); *Walston*, 923 P.2d at 462 (the out-of-pocket rule "limits the recovery of damages to the difference between the real value of the property purchased and the price paid or contracted for") (citation omitted). Dr. Conti's "worthlessness" theory cannot be used to support Plaintiffs' common law fraud claims under these standards because it fails to "consider[] the therapeutic value of the products[.]" (Dkt # 3018 at 45.)

Second, Plaintiffs' consumer protection claims also require evidence of the relevant VCDs' actual value. For starters, nearly all of the state consumer protection statutes at issue (17 of 18) expressly require the plaintiff to prove injury—i.e., an "ascertainable loss" and/or "actual damages." *See, e.g.*, Conn. Gen. Stat. § 42-110g(a) ("Any person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment of a method, act or practice prohibited by section 42-110b, may bring an action in the judicial district in which the plaintiff or defendant resides or has his principal place of business or is doing business, to recover actual damages."); N.H. Rev. Stat. § 358-A:10(I) ("If the court finds for the plaintiff, recovery shall be in the amount of actual damages or $1,000, whichever is greater. If the court finds that the use of the method of competition or the act or practice was a willful or knowing violation of this chapter, it shall award as much as 3 times, but not less than 2 times, such amount."). (*See also* Ex. B (Assessment of TPP Consumer Protection Subclass Group A).) Under the logic of the Court's prior ruling, this injury element necessarily entails an assessment of the actual value of the good received. (*See* Dkt # 3018 at 46 ("Plaintiffs[] fail[] to appreciate the critical distinction between alleging an injury in fact for standing, sustaining an injury as an element of the claim to establish liability, and then proving the injury to calculate damages.").)

Federal courts applying the law of the relevant states' consumer protection statutes have explicitly held that a "full refund model" is improper to measure damages in circumstances where, as here, the product did convey a benefit to class members. *See Corbett v. PharmaCare U.S. Inc.*, No. 21-cv-137-JES (AHG), 2024 WL 1356220, at *15, *24-25 (S.D. Cal. Mar. 29, 2024). In *Corbett*, the plaintiffs premised their consumer protection claims under California and Missouri law on the allegation that the defendants misbranded their dietary supplement in violation of the

Food Drug & Cosmetics Act. *Id.* at *15. Like the TPP Plaintiffs here, they asserted that a full refund model was appropriate because a misbranded product is illegal and hence valueless. *Id.* at *25. The court rejected that model, finding that the general rule is that consumers can only recover the difference between what the plaintiff paid and the value actually received. *Id.* (collecting cases).

Similarly, in *Shahinian v. Kimberly-Clark Corp.*, the court rejected a "full refund damages model" for a claim asserted under California's Unfair Competition Law based on the sale of allegedly misbranded and defective surgical gowns because there was evidence showing the "gowns have other valuable attributes" and were not "useless to class members." No. 14-8390, 2016 WL 11722907, at *13-15 (C.D. Cal. Nov. 14, 2016); *see also Caldera v. J.M Smucker Co.*, No. 12-4936, 2014 WL 1477400, at *4 (C.D. Cal. Apr. 15, 2014) (holding that "a full refund would only be appropriate" under California's consumer protection statutes "if not a single class member received any benefit from the products").

In addition, courts interpreting the consumer protection laws of at least 6 of the 18 states at issue have held that consumer protection damages must account for the actual value received or benefits conferred. *See, e.g.*, *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 131 (2009) (finding restitution remedy under California consumer protection statutes is measured by "[t]he difference between what the plaintiff paid and the value of what the plaintiff received"); *Rollins, Inc. v. Heller*, 454 So. 2d 580, 585 (Fla. Dist. Ct. App. 1984) (under the Florida Deceptive and Unfair Trade Practices Act, "the measure of actual damages is the difference in the market value of the product or service in the condition in which it was delivered and its market value in the condition in which it should have been delivered according to the contract of the parties"); *Hennessey v. Gap, Inc.*, 86 F.4th 823, 829 (8th Cir. 2023) ("Missouri courts generally apply the common-law 'benefit of the bargain' rule to determine whether an [Missouri Merchandising Practices Act] plaintiff has suffered an ascertainable loss" and that rule "awards a prevailing party the difference between the value of the product as represented and the actual value of the product as received") (citation omitted); *Harris v. Poche*, 930 So. 2d 165, 172 (La. Ct. App. 2006) ("[W]e agree with the trial court that once the Harrises proved a claim under the Unfair Trade Practices Act, then at that time they were entitled to seek damages for the difference between the purchase price of the home in November 2001, and the appraised value of the home at the time of trial."); *Borgen v. A&M Motors, Inc.*, 273 P.3d 575, 592 (Alaska 2012) (finding no issue with jury instruction on damages in an Alaska Unfair Trade Practices and Consumer Protection Act case that instructed the jury "to evaluate the difference [in value between the motor home as represented and as it actually was] as of the time of purchase in 2004"); *Stokes v. Gary Barbera Enters.*, 783 A.2d 296, 299 (Pa. Super. Ct. 2001) (affirming damage award under Pennsylvania's consumer protection statute in a case concerning a car dealer's misrepresentation where damages were reduced by the plaintiff's use of the car and its trade-in value). (*See also* Appendix B.)

In short, Dr. Conti's methodologically flawed theory is also incapable of establishing damages under the applicable state consumer protection statutes, which generally require an assessment of the actual value of the product as received.

3. ZHP's Certificates of Analysis, Material Safety Data Sheets, and Other Discovery

A. A Corporate Representative Deposition Related to Certificates of Analysis and Material Safety Data Sheets Is Unwarranted.

Yesterday, April 23, 2025, Plaintiffs alerted ZHP that they intend to seek a Rule 30(b)(6) deposition related to the certificates of analysis ("COAs"), material safety data sheets ("MSDSs"), and other documents recently produced by ZHP. ZHP does not believe that any additional depositions are warranted or appropriate at this stage of the litigation, particularly in light of the circumstances present here.

By way of background, ZHP identified Dr. Jinsheng Lin as a potential trial witness months in advance of the TPP trial that was scheduled to begin in October 2024. Plaintiffs asked the Court to bar Dr. Lin from testifying at that trial. While the Court rejected that request, it gave Plaintiffs leave to depose Dr. Lin in advance of his trial testimony. In advance of that deposition, which has not yet occurred, Plaintiffs requested that ZHP produce certain COAs and MSDSs pertaining to certain raw materials used in the valsartan API manufacturing process, despite the fact that Dr. Lin does not generally review these materials in the course of his work and has no recollection of reviewing the particular COAs and MSDSs requested by Plaintiffs. ZHP has searched for and produced all of the relevant COAs and MSDSs located in its files. Plaintiffs now want a 30(b)(6) deposition about these documents before deposing Dr. Lin. At some point, however, Plaintiffs' continued efforts to reopen discovery have to come to an end.

Nevertheless, in the spirit of compromise, and without waiving its objections to ongoing discovery requests, ZHP agrees to consider a narrowly tailored Rule 30(b)(6) notice related to the produced COAs and MSDSs. ZHP will meet and confer in good faith with Plaintiffs' counsel regarding such a notice, and if the parties are unable to reach agreement, ZHP will file a motion for a protective order setting forth its position in more detail.

B. The Court Has Already Considered and Appropriately Rejected Plaintiffs' Request for Leave to File a Sanctions Motion Related to the Production of COAs and MSDSs.

In the same April 23, 2025 email in which Plaintiffs told ZHP's counsel that they intend seek a Rule 30(b)(6) deposition related to the produced COA and MSDS documents, Plaintiffs also indicated they intend to again seek leave to file a motion for sanctions—presumably on the basis that ZHP should have produced the COA and MSDS documents earlier in the litigation or should have COA/MSDS documents dated prior to December 2015 available for production. As the Court made clear during the March 3, 2025 Case Management Conference, a motion for sanctions is unwarranted absent some showing that Plaintiffs were intentionally misled about whether these documents existed and that Plaintiffs were prejudiced by not receiving the documents sooner. (*See* 3/3/2025 CMC Tr. 36-37.)

Plaintiffs cannot make either showing. There is no evidence that ZHP intentionally misled Plaintiffs as to whether the Company maintained any COAs or MSDSs. When Plaintiffs made a

request for these documents in December 2024, in connection with the anticipated deposition of Dr. Lin, ZHP explained that these were not the kinds of documents that Dr. Lin would typically review in the ordinary course of his work, but expressed its willingness to meet and confer with Plaintiffs to determine whether there were ways to minimize the burdens associated with production of these materials. (*See* 12/3/2024 Email from M. Hansen to C. Geddis (attached as Ex C).) ZHP has never misrepresented to counsel that COAs or MSDSs did not exist. In addition, Plaintiffs now have the documents at issue and therefore have not suffered any prejudice given that the first trial in this litigation is still many months away. Moreover, to the extent Plaintiffs are claiming prejudice because ZHP does not have in its possession COAs received prior to December 2015, there is zero evidence that these earlier COAs were materially different from the hundreds of COAs ZHP received after 2015 and has produced. To the contrary, the COAs that ZHP would have received prior to 2015—like those produced—would have had to be consistent with the requirements set forth in the applicable industry standard, which sets the minimum requirements for sale of that chemical in China.

In short, because ZHP did not intentionally withhold any documents, and because Plaintiffs now have—many months before trial—all of the available documents sought, Plaintiffs' request for leave to file a motion for sanctions should be denied.

4. Finalized Orders on Rule 702 and MIL Rulings Related to TPP Trial

The parties are in the process of meeting and conferring in an effort to reach agreement on the language of the relevant Orders. Defendants' current version of the proposed Rule 702 Orders are attached hereto as Ex. D (Stiroh and Gibson), and Ex. E (Afnan). Defendants also attach the current versions of Orders on the Omnibus Motions in Limine as Ex. F (Defendants' Revisions to Plaintiffs' MIL Order) and Ex. G (Defendants Revisions to Defendants' MIL Order).

5. Defendants' DFS Updates for Wave 2 Bellwether Cases

The Parties have agreed that ZHP and Teva will produce amended Defendant Fact Sheets for each of the Wave 2 cases by May 2, 2025. The amended Defendant Fact Sheets will contain testing levels in the form that was done in the Roberts case.

6. Plaintiff Fact Sheet Deficiencies

Cases Addressed at the March 28, 2025 Case Management Conference:

The Court issued eleven orders to show cause returnable at the April 28, 2025 Case Management Conference:

1. *Edron Harris v. Doe* – 24-cv-546
2. *Robert Jaskulski v. Aceteris, LLC, et al*. – 24-cv-5752
3. *Mark McNall v. Aurobindo, et al*. – 23-cv-21327
4. *Teresa Esrig v. Torrent, et al*. – 22-cv-244

5. *Yolanda Williams v. Hetero, et al*. – 24-cv-7899
6. *Soraya Svoronos v. Torrent, et al*. – 23-cv-22220
7. *Harry Wicks v. ZHP, et al*. – 24-cv-6188
8. *Shirley Thomas v. Aurobindo Pharma, Ltd., et al*. – 23-cv-01700
9. *Estate of Betty Baker v. Teva, et al*. – 20-cv-17108
10. *Christopher Hurst v. Teva, et al*. – 23-cv-20308
11. *George Stokes v. ZHP, et al*. – 21-cv-20419

The issues in the *Harris* and *Jaskulski* matters are resolved, and the orders to show cause in these two matters may be withdrawn.

The issues in the *McNall*, *Esrig*, and *Williams* matters remain unresolved, but the parties agree to an extension of the orders to show cause in these three matters until the next case management conference.

The issues in the *Svoronos*, *Wicks*, *Thomas*, *Baker*, *Hurst*, and *Stokes* matters remain unresolved, and Defendants request the dismissal of these matters.

Second Listing Cases – Order to Show Cause Requested:

Defendants are not requesting new orders to show cause returnable at the next case management conference be issued in any matters where such an order is not already pending.

First Listing Cases – Remaining Core Deficiencies:

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs' leadership on April 16, 2025, and a meet and confer was held on April 23, 2025. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	**Civil Action No.**	**Law Firm**	**Deficiencies**	**Deficiency Sent**
1.	Russell, Kevin	25-cv-00278	Nigh Goldenberg Raso & Vaughn	No pharmacy records	4/1/25

2.	James Doherty v. Aurobindo, et al.	25-cv-956	Bernstein Liebhard	No PFS Filed	PFS Due – 4/3/25
3.	Ladawn Banks v. Aurobindo, et al.	25-cv-1159	Stark & Stark	No PFS Filed	PFS Due – 4/11/25
4.	Roger Fast v. Aurobindo, et al.	25-cv-1192	Stark & Stark	No PFS Filed	PFS Due – 4/12/25
5.	Larry Langsbard v. ZHP, et al.	25-cv-1294	Nigh Goldenberg	No PFS Filed	PFS Due – 4/17/25
6.	Ronald Gies v. Hetero Drugs, et al.	25-cv-1186	Bernstein Liebhard	No PFS Filed	PFS Due – 4/21/25
7.	Billy McGee v. ZHP, et al.	25-cv-1532	Nigh Goldenberg	No PFS Filed	PFS Due – 4/28/25
8.	Randy Harris v. Aurobindo Pharma, Ltd.	25-cv-1562	Levin Papantonio	No PFS Filed	PFS Due – 4/28/25

7. Product Identification Deficiencies

Cases Addressed at the March 28, 2025 Case Management Conference:

Institution of a product identification show cause process was an agenda item at the March 3, 2025 Case Management Conference ("CMC"). Since that time, the Court entered CMO-38 instituting a

show cause process which began at the March 28, 2025 CMC. As this is only the second CMC since the entry of CMO-38, only "Second" and "First Listing" cases are on this month's agenda, and no show cause orders are currently returnable.

Pending Order(s) to Show Cause – N/A

Second Listing Cases – Order to Show Cause Requested:

The following product identification issues remain unresolved. This list was provided to Plaintiffs' leadership on April 16, 2025, and a meet and confer was held on April 23, 2025. Defendants have also been available for further discussion as needed. This is the second time these cases have been listed on this agenda. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed with respect to the requesting Defendants.

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
1. John Avjian	24-cv-09463	Kendra Goldhirsch Chaffin Luhana LLP	Mylan Laboratories Ltd., Mylan N.V., and Mylan Pharmaceuticals Inc.	December 2024
2. Dixie Buxton	23-cv-02933	David Hobbs Fleming, Nolen & Jez, L.L.P.	Mylan Pharmaceuticals Inc., Mylan N.V., and Mylan Laboratories Ltd.	August 2023
3. Edward Jackson	20-cv-6589	David Hobbs Fleming, Nolen & Jez, L.L.P.	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V.	March 2024
4. Priscilla Kleinman	19-cv-7152	Watts Law Firm LLP	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc.	March 2024

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
5. Christopher Lang	24 -cv-8254	Kendra Goldhirsch Chaffin Luhana LLP	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc.	October 2024
6. Shylaine Louissaint	21-cv-7797	Andrew O'Conner Nagel Rice	Mylan Laboratories Ltd.	November 2022
7. Kevin Russell	25-cv-00278	Nigh Goldenberg Raso & Vaughn	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V.	March 2025
8. Janet Snipe	24 -cv-04013	Kendra Goldhirsch Chaffin Luhana LLP	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V.	October 2024
9. Diane Troiano John Troiano	20-cv-2341	Michael Schafle Green & Schafle LLC	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.	October 2022 (Mylan) 9/29/23; 2/25/25 (Teva)

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
10. Catherine Worsham	22-cv-00002	Morgan and Morgan	Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V.	March 2024
11. Bykowski, Leslie	20-cv-14248	Watts Guerra	Arrow Pharm (Malta) Ltd.	4/26/24; 2/25/25
12. Ernsbarger, Loren	20-cv-18796	Fleming, Nolen & Jez, LLP	Arrow Pharm (Malta) Ltd. and Teva Pharmaceuticals USA, Inc.	5/3/24; 2/25/25
13. Franklin, Jerry (Est. of Billye)	20-cv-7860	Michael Brady Lynch Firm	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis, LLC; Actavis Pharma, Inc.; Arrow Pharm (Malta) Ltd.	10/10/24; 2/25/25
14. Montalbano, Annette	23-cv-22904	The Barnes Firm	Arrow Pharm (Malta) Ltd..	3/3/25

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
15. Mottie, Maurice	22-cv-06304	Fleming, Nolen & Jez, LLP	Teva Pharmaceuticals USA, Inc.	5/3/24; 2/26/25
16. Peyton, Katherine	21-cv-09063	DeGaris	Teva Pharmaceutical Industries, Ltd.	5/3/24; 2/26/25
17. Polita, Adelaide o/b/o Frank Annunziato	20-cv-7879	Michael Brady Lynch Firm	Arrow Pharm (Malta) Ltd.	10/20/23; 2/26/25
18. Sanders, Ada	20-cv-7884	Michael Brady Lynch Firm	Teva Pharmaceuticals USA, Inc.	10/20/23; 2/26/25
19. Smoot, Lee	20-cv-7994	Michael Brady Lynch Firm	Arrow Pharma (Malta) Ltd.	10/10/23; 2/26/25

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
20. Stiles, Debra	22-cv-1987	Pittman Dutton	Arrow Pharm (Malta) Ltd.	10/27/23; 2/26/25
21. Taggart, Joyce	20-cv-8802	Fleming, Nolen & JEZ, LLP	Teva Pharmaceuticals USA, Inc.	5/3/24; 2/26/25
22. Taylor, Barbara	21-cv-19430	Fleming, Nolen & JEZ, LLP	Teva Pharmaceuticals USA, Inc.	5/3/24; 2/26/25
23. Thomas, Jason	20-cv-15091	Scott Morgan	Teva Pharmaceuticals USA, Inc.	10/20/23; 2/26/25
24. Thornton, Ricky	20-cv-16078	Watts Guerra	Arrow Pharm (Malta) Ltd.	4/26/24; 2/26/25

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
25. Tippett, Gary	22-cv-00826	Pittman Dutton	Arrow Pharm (Malta) Ltd., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.	9/29/23; 2/26/25
26. Tolley, Margaret	21-cv-10130	DeGaris	Teva Pharmaceuticals USA, Inc.	5/3/24; 2/26/25
27. Torghele, Daniel	19-cv-21034	Shrager, Spivey & Sachs	Arrow Pharm (Malta) Ltd.	10/20/23; 2/26/25
28. Vindigni, Richard	21-cv-02361	Julian Bailey	Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc.	5/31/24; 2/26/25
29. Williams, Ernestine	21-cv-6946	Douglas & London	Teva Pharmaceuticals USA, Inc.	5/3/24; 2/26/25

First Listing Cases – Remaining Product Identification Deficiencies:

The following product identification issues remain unresolved. This list was provided to Plaintiffs' leadership on April 16, 2025, and a meet and confer was held on April 23, 2025. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
1. Avjian, John	24-cv-09463	Kendra Goldhirsch Chaffin Luhana LLP	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis, LLC	3/28/25
2. Cleveland, Michael	20-cv-00950	Morgan & Morgan	Teva Pharmaceuticals USA, Inc.	3/28/25
3. Fryer, Pamela	24-cv-4243	Chaffin Luhana LLP	Teva Pharmaceuticals USA, Inc.; Arrow Pharm (Malta) Ltd.	3/31/25

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
4. Jaskulski, Robert	24-cv-5752	Nigh Goldenberg	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis, LLC; Actavis Pharma, Inc.; Arrow Pharm (Malta) Ltd. Mylan N.V., Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd.	3/31/25 (Teva) 4/1/25 (Mylan)
5. Keller, Theodore	20-cv-6918	Shrager & Sachs	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Actavis, LLC; Actavis Pharma, Inc.	3/31/25
6. Lang, Christopher	24-cv-8254	Chaffin Luhana LLP	Teva Pharmaceutical Industries, Ltd.	3/31/25
7. Lee, David	24-cv-9107	Chaffin Luhana LLP	Teva Pharmaceutical Industries, Ltd.; Actavis, LLC	3/31/25

Plaintiff	Docket	Attorney	Entity(ies) to be Dismissed	Prior Dismissal Request(s)
8. Mcelheny, Shawn	24-cv-6971	Chaffin Luhana LLP	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Arrow Pharm (Malta) Ltd.	3/31/25
9. McMurray, Leda Kay (Robert)	20-cv-07174	Fleming Nolen	Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.	4/1/25
10. Snipe, Janet	24-cv-04013	Chaffin Luhana LLP	Teva Pharmaceuticals USA, Inc.	4/1/25
11. Stern, Jeannette	24-cv-9402	Bernstein Liebhard LLP	Arrow Pharm (Malta) Ltd.	4/1/25
12. Thomas, Shirley	23-cv-01700	Terrell Hogan Yegelwel, P.A	Mylan N.V., Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd.	4/1/25

Respectfully submitted,

Clem C. Trischler

c: All counsel of record (via ECF)